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10/776,021	02/09/2004	Ramez Emile Necola Shchada	064693-0103	9078

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EXAMINER

HAND, MELANIE JO

ART UNIT	PAPER NUMBER
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3761

MAIL DATE	DELIVERY MODE
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07/09/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/776,021

Applicant(s)

SHEHADA, RAMEZ EMILE
NECOLA

Examiner

Melanie J. Hand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1 and 3-15 have been considered but are moot in view of the new ground(s) of rejection.

With respect to applicant's arguments regarding the rejection of claims 1, 3-6 and 9-11 as anticipated by Jenkins: Applicant argues that Jenkins does not teach a conduit that is configured to rest against but not penetrate the tissue of the body. Jenkins teaches that the instant device does not penetrate the tissue of the body as can best be seen in Figs. 1 and 12A. It is unclear what applicant's basis is for arguing that the device of Jenkins "penetrates" the pulmonary vein. If by penetrate it is meant that the device enters the vein, then applicant's argument is correct. Applicant has not provided support in the disclosure for this amendment, therefore not only is there no support, there is no definition for "penetrate" that would contradict the widely understood definition. In this case, that widely understood definition would be applied as meaning that the device of Jenkins creates an opening in the vein or tissue so as to extend through it, which said device does not do. Jenkins also teaches at least one sensing elements 104, 106.

Applicant further argues that the inflatable compartment of Jenkins is not positioned behind the sensing element 104. Applicant is directed to Fig. 10A where it is clear that inflatable compartment 118 is behind sensing element 104 and is configured to push the sensing element against the tissue.

Applicants' arguments with regard to dependent claims 7 and 12-15 have been fully considered but are not persuasive as Applicants' arguments depend entirely on applicants' arguments regarding the rejection of claim 1, which have been addressed *supra*.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the disclosure as originally filed for an elongated conduit configured to rest against but not penetrate the tissue of the body.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-6 and 9-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Jenkins et al (U.S. Patent No. 6,645,199).

With respect to **claim 1**: Jenkins teaches an implantable surgical drain having a contact optimizer when placed against a tissue of a patient's body for draining fluid and sensing at least one physiological property of the tissue comprising: an elongated conduit 114 configured to be implanted in a patient's body and to rest against but not penetrate the tissue of the body to drain fluid from the body, the elongated conduit 114 including a first and a second surface on an outer

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side of the elongated conduit 114 (Fig. 10A, Col. 11, lines 52-56); at least one sensing element 104 positioned at the first surface of the elongated conduit 114 configured to sense a physiological property of the tissue, and a first inflatable compartment 118 positioned between the first and the second surfaces of said conduit 114 configured to optimize contact between the tissue and the first sensing element 104. (see Abstract)

With respect to **claim 3**: As seen in Fig. 2, Jenkins teaches inflatable compartment 18 located within elongated conduit 20.

With respect to **claim 4**: As can be seen in Fig. 12A, the first sensing system element 104 located on loop structure 14 and first inflatable compartment 118 are positioned at about the same position along a drain length.

With respect to **claim 5**: The physiological property is temperature. (Col. 16, lines 32-34)

With respect to **claim 6**: A second sensing system element 106 is used as a mapping element and is thus configured to sense a different physiological property than the first sensing system element 104. (Col. 11, lines 27-30)

With respect to **claim 9**: Jenkins implicitly describes a pump in communication with an interior portion of the inflatable compartment. (Col. 11, line 65 - Col. 12, line 3) Jenkins teaches that "pressure is maintained to maintain the inflatable push structure 118 in the expanded orientation in Fig. 10A. This maintenance of the expanded configuration of inflatable compartment 118 can

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only be accomplished by a pump structure, even though Jenkins does not make specific mention of a pump.

With respect to **claim 10**: Jenkins also implicitly describes a pressure monitor in communication with the interior portion of the inflatable chamber by teaching that "pressure is maintained to maintain the inflatable push structure 118 in the expanded orientation in Fig. 10A". (Col. 12, lines 1-3)

With respect to **claim 11**: The surgical drain further includes an anchor 128 configured to stabilize the position of the surgical drain relative to the tissue in the body. (Col. 12, lines 43-47)

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins et al ('199) in view of Fiddian-Green (U.S. Patent No. 6,334,064).

With respect to **claim 7**: The elongated conduit 114 taught by Jenkins does not include a drain portion. Fiddian-Green teaches a plurality of drain holes 74 or 274 on conduit 22 that are spaced along substantially the entire length of, and define, a drain portion. Such portion is configured to rest against a substantial length of tissue within the body through which a stomach or bladder may be aspirated. (Col. 6, lines 57-59, Col. 10, lines 32-34) Since the devices of Jenkins and Fiddian-Green seek to solve a similar problem, it would be obvious to one of

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ordinary skill in the art to modify the device of Jenkins so as include a drain portion comprising a plurality of drain openings spaced along substantially the entire length of the drain portion as taught by Fiddian-Green.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins et al ('199).

With respect to **claim 8**: Jenkins teaches a PC board and a connector port 129 (Col. 12, lines 55,56) and signals transmitted to said PC board from the temperature sensors for control purposes (Col. 16, lines 35-38), but does not explicitly teach a display configured to depict data corresponding to the physiological property sensed by the first sensing system element. However, given that data is created, collected and potentially used for tissue mapping purposes as taught by Jenkins, it would be obvious to one of ordinary skill in the art to include a display configured to depict such data.

Claims 12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins et al ('199) in view of Wittes et al (U.S. Patent No. 3,680,562).

With respect to **claim 12**: The surgical drain taught by Jenkins does not include a projection extending from the outer side, wherein the projection is configured for insertion into tissue in the body cavity. Wittes teaches bifurcated wings 40,40' that are bent away from catheter tube 28 (i.e. extending from the outer side) and affixed to the skin to anchor catheter 32 via sutures after said tubing is implanted within a patient's bladder (thus being configured for insertion into tissue in the body). Wittes teaches that catheter 32 is indwelling and designed to contact tissue, it

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would be obvious to one of ordinary skill in the art to modify the device taught by Jenkins such that the elongated conduit includes a projection extending from its outer side as taught by Wittes.

With respect to **claim 15**: The surgical drain taught by Jenkins does not include a flap extending from the outer side. Wittes teaches a catheter 32 comprising a sheath 38 bifurcated into half-tube wings 40,40' (flap) that serves as an anchoring means. Since Wittes teaches that catheter 32 is indwelling and designed to contact tissue as is the device of Jenkins, both devices seek to solve a similar problem and thus it would be obvious to one of ordinary skill in the art to modify the elongated conduit taught by Jenkins to include a flap as taught by Wittes.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins et al ('199) in view of Torre et al (U.S. Patent Application Publication No. 2002/0055757).

With respect to **claim 13**: The surgical drain taught by Jenkins does not include a first loop extending from the outer side. Torre teaches an intragastric endoscope 10 having a loop on its surface for manipulation, deflation and/or removal of said endoscope. (¶ 0016) Jenkins is teaching a device that seeks to solve a similar problem (i.e. anchoring the device near tissue to evaluate physiological properties of the tissue for treatment) to the device taught by Torre. The methods employed to manipulate the respective devices of Jenkins (inflatable compartment) and Torre (surface loop) are substantially equivalent and effect the same end result, i.e. manipulation, and/or removal of an elongated conduit. Thus it would be obvious to one of ordinary skill in the art to substitute the inflatable compartment taught by Jenkins with the loop taught by Torre with a reasonable expectation of success.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkins et al ('199) in view of Schoolman (U.S. Patent No. 5,215,539).

With respect to **claim 14**: Jenkins does not teach that the surgical drain further includes adhesive on at least a portion of the outer side. Schoolman teaches a vacuum strip apparatus for surgical incisions comprising an elongate hollow strip 6 comprising a plurality of openings 28 (Col. 4, lines 61-66) and double-sided adhesive tape 41 on its engagement surface 39 for adhesion to a patient's skin 22. (Fig. 1) (Col. 5, lines 16,17,25-30) The devices taught by Jenkins and Schoolman seek to solve a similar problem, i.e. anchoring the device near tissue to evaluate physiological properties of the tissue for treatment. The methods employed to anchor each device by Jenkins (inflatable compartment 118) and Schoolman (adhesive tape on a tissue engagement surface) are substantially equivalent and effect the same end result, i.e. anchoring an elongated conduit adjacent a desired tissue site in the body. Thus it would be obvious to one of ordinary skill in the art to substitute the inflatable compartment taught by Jenkins with adhesive tape on the outer surface of said elongated conduit as taught by Schoolman with a reasonable expectation of success.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
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June 25, 2007

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read 'Tatyana', written in a cursive style.